

EXHIBIT 10

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

: MDL NO. 2875

IN RE: VALSARTAN,
LOSARTAN, AND IRBESARTAN
PRODUCTS LIABILITY
LITIGATION

:
:
:
: VIDEOTAPED DEPOSITION
:
: UPON
:
: ORAL EXAMINATION
:
: OF
:
: RAMIN (RON) NAJAFI,
X Ph.D., VOLUME II

TRANSCRIPT of the stenographic notes of
the proceedings in the above-entitled matter, as
taken by and before ELLEN J. GODINO, CCR, RPR, CRCR,
held via ZOOM VIDEOCONFERENCE from various locations,
with the witness located at 1000 Atlantic Avenue,
Suite 110, Alameda, California, on Wednesday, January
24, 2023, commencing at 8:10 a.m. Pacific Time.

<p style="text-align: right;">Page 266</p> <p>1 A P P E A R A N C E S:</p> <p>2 FOR PLAINTIFFS:</p> <p>3</p> <p>4 MAZIE SLATER KATZ & FREEMAN</p> <p>5 BY: CHRISTOPHER J. GEDDIS, ESQ.</p> <p>6 103 Eisenhower Parkway</p> <p>7 2nd Floor</p> <p>8 Roseland, New Jersey 07068</p> <p>9 973-228-9898</p> <p>10 cgeddis@mazieslater.com</p> <p>11</p> <p>12 LEVIN PAPANTONIO RAFFERTY</p> <p>13 BY: DANIEL NIGH, ESQ.</p> <p>14 316 South Baylen Street</p> <p>15 Pensacola, Florida 32502</p> <p>16 850-435-7013</p> <p>17 dnigh@levinlaw.com</p> <p>18</p> <p>19 FOR ZHEJIANG HUAHAI PHARMACEUTICAL, CO., LTD.:</p> <p>20 SKADDEN ARPS SLATE MEAGHER & FLOM, LLP</p> <p>21 BY: NINA R. ROSE, ESQ.</p> <p>22 ALEXANDER J. KASPARIE, ESQ.</p> <p>23 One Manhattan West</p> <p>24 New York, New York 10001-8602</p> <p>25 212-735-3000</p> <p>nina.rose@skadden.com</p> <p>alexander.kasparie@skadden.com</p> <p>FOR TEVA PHARMACEUTICALS USA, INC., TEVA</p> <p>PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS PHARMA, INC.,</p> <p>AND ACTAVIS LLC:</p> <p>GREENBERG TRAURIG, LLP</p> <p>BY: STEVEN M. HARKINS, ESQ.</p> <p>Terminus 200</p> <p>3333 Piedmont Road NE, Suite 2500</p> <p>Atlanta, Georgia 30305</p> <p>678-553-2100</p> <p>harkinss@gtlaw.com</p>	<p style="text-align: right;">Page 268</p> <p>1 A P P E A R A N C E S (Continued):</p> <p>2 FOR HETERO LABS, LTD:</p> <p>3 HILL WALLACK, LLP</p> <p>4 BY: WILLIAM P. MURTHA, JR., ESQ.</p> <p>5 777 Township Line Road</p> <p>6 Suite 250</p> <p>7 Yardley, Pennsylvania 19067</p> <p>8 267-759-2064</p> <p>9 wmurtha@hillwallack.com</p> <p>10 LEVIN PAPANTONIO RAFFERTY</p> <p>11 BY: DANIEL NIGH, ESQ.</p> <p>12 316 South Baylen Street</p> <p>13 Pensacola, Florida 32502</p> <p>14 850-435-7013</p> <p>15 dnigh@levinlaw.com</p> <p>16</p> <p>17 FOR DEFENDANT SCIEGEN PHARMACEUTICALS, INC:</p> <p>18</p> <p>19 HINSHAW & CULBERTSON, LLP</p> <p>20 BY: GEOFFREY M. COAN, ESQ.</p> <p>21 53 State Street</p> <p>22 Boston, Massachusetts 02109</p> <p>23 617-213-7045</p> <p>24 617-213-7001</p> <p>25 gcoan@hinshawlaw.com</p> <p>ALSO PRESENT:</p> <p>BEN PELTA-HELLER, Videographer</p>
<p style="text-align: right;">Page 267</p> <p>1 A P P E A R A N C E S (Continued):</p> <p>2 MARTIN, HARDING & MAZZOTTI, LLP</p> <p>3 BY: ROSEMARIE RIDDELL BOGDAN, ESQ.</p> <p>4 P.O. Box 15141</p> <p>5 23 Albany, New York 12212</p> <p>6 518-724-2207</p> <p>7 Rosemarie.bogdan@1800law1010.com</p> <p>8</p> <p>9 FOR PFIZER INC., VALEANT PHARMACEUTICALS</p> <p>10 INTERNATIONAL, INC., BAUSCH & LOMB INCORPORATED, AND</p> <p>11 ATON PHARMA, INC.:</p> <p>12 WALSH PIZZI O'REILLY FALANGA, LLP</p> <p>13 BY: CHRISTINE I. GANNON, ESQ.</p> <p>14 Three Gateway Center</p> <p>15 100 Mulberry Street, 15th Floor</p> <p>16 Newark, New Jersey 07102</p> <p>17 973-757-1100</p> <p>18 cgannon@walsh.com</p> <p>19</p> <p>20 FOR MYLAN PHARMACEUTICALS INC., AND MYLAN</p> <p>21 LABORATORIES, LTD.:</p> <p>22 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP</p> <p>23 BY: FRANK. H. STOY, ESQ.</p> <p>24 One Oxford Centre</p> <p>25 301 Grant Street, 38th Floor</p> <p>Pittsburgh, Pennsylvania 15219</p> <p>412-263-4397</p> <p>fhs@pietragallo.com</p> <p>FOR TORRENT PHARMA INC. & TORRENT PHARMACEUTICALS,</p> <p>LTD.:</p> <p>KIRKLAND & ELLIS, LLP</p> <p>BY: BRITTNEY NAGLE, ESQ.</p> <p>601 Lexington Avenue</p> <p>New York, New York 10022</p> <p>212-390-4210</p> <p>brittney.nagle@kirkland.com</p>	<p style="text-align: right;">Page 269</p> <p>1 I N D E X</p> <p>2</p> <p>3 Examinations Page</p> <p>4</p> <p>5 R A M I N (R O N) N A J A F I , Ph.D.</p> <p>6 271</p> <p>7 EXAMINATION BY MS. ROSE</p> <p>8 271</p> <p>9 EXAMINATION BY MR. HARKINS 295</p> <p>10</p> <p>11 EXAMINATION BY MS. NAGLE 341</p> <p>12</p> <p>13 E X H I B I T S</p> <p>14</p> <p>15 NumberDescription Page</p> <p>16 Najafi-16 Article entitled "Theoretical 279</p> <p>17 Investigation of</p> <p>18 N-nitrosodimethylamine</p> <p>19 Formation from Nitrosation of</p> <p>20 Trimethylamine," by Zhi Sun et</p> <p>21 al. from The Journal of</p> <p>22 Physical Chemistry, previously</p> <p>23 marked ZHP-211</p> <p>24</p> <p>25 Najafi-17 Article entitled 284</p> <p>"Ester-Mediated Nitrosamine</p> <p>Formation from Nitrite and</p> <p>Secondary or Tertiary Amines,"</p> <p>by R.N. Loeppky et al., from</p> <p>IARC Scientific Publications,</p> <p>No Bates, 11 Pages</p>

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<p>1 EXHIBITS (Continued)</p> <p>2</p> <p>3 Number Description Page</p> <p>4 Najafi-18 FDA Document entitled 333</p> <p>5 "Guidance for Industry, Q3A</p> <p>6 Impurities in New Drug</p> <p>7 Substances," Revision 2 dated</p> <p>8 June 2008, No Bates, 17 Pages</p> <p>9 Najafi-19 FDA Document entitled 340</p> <p>10 "Guidance for Industry,</p> <p>11 Q3B(R2) Impurities in New Drug</p> <p>12 Products," Revision 3, August</p> <p>13 2006, No Bates, 18 Pages</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 software open on your computer?</p> <p>2 A. No, I don't.</p> <p>3 Q. You don't have any mail or messaging</p> <p>4 software open?</p> <p>5 A. (No audible response.)</p> <p>6 Q. I'm sorry, I didn't hear that.</p> <p>7 A. No, I don't.</p> <p>8 Q. Will you agree not to email, message or</p> <p>9 have any other private communications with anyone</p> <p>10 while we are on the record?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Will you agree not to open any documents</p> <p>13 on your computer, other than the ones you may be</p> <p>14 shown on the Veritext platform?</p> <p>15 A. Yes, I will.</p> <p>16 Q. Have you had any alcoholic drinks in the</p> <p>17 past eight hours?</p> <p>18 A. No, I have not.</p> <p>19 Q. Are you on any medication that would</p> <p>20 prevent you from providing accurate testimony?</p> <p>21 A. No, I do not.</p> <p>22 Q. Is there any other reason you cannot</p> <p>23 give complete and accurate testimony today?</p> <p>24 A. No.</p> <p>25 Q. Since the last session of your</p>
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<p>1 THE VIDEOGRAPHER: Good morning. We are</p> <p>2 going on the record at 8:10 a.m. on Tuesday,</p> <p>3 January 24, 2023. This begins Media Unit 1 of the</p> <p>4 video-recorded deposition of Dr. Ron Najafi,</p> <p>5 Volume II, taken by counsel in the matter of In Re:</p> <p>6 Valsartan.</p> <p>7 My name is Ben Pelta-Heller,</p> <p>8 representing Veritext, and I'm the videographer. The</p> <p>9 court reporter is Ellen Godino, from the firm</p> <p>10 Veritext.</p> <p>11 All counsel will be noted on the</p> <p>12 stenographic record, and will the reporter please</p> <p>13 swear in the witness.</p> <p>14 R A M I N (R O N) N A J A F I, Ph.D., having</p> <p>15 been duly sworn, testified as follows:</p> <p>16 EXAMINATION BY MS. ROSE:</p> <p>17 Q. Hi, Dr. Najafi. Good to see you again.</p> <p>18 A. It's good to see you, too.</p> <p>19 Q. Today we are continuing the deposition</p> <p>20 that began on January 18, 2023. Correct?</p> <p>21 A. That is correct.</p> <p>22 Q. And because it's a new day, I'm going to</p> <p>23 reconfirm a few things we went over with the first</p> <p>24 deposition.</p> <p>25 Aside from Zoom, do you have any other</p>	<p>1 deposition, have you spoken with the plaintiffs'</p> <p>2 lawyers in this case?</p> <p>3 A. Yes, I have.</p> <p>4 Q. How many times?</p> <p>5 A. I would say a couple times.</p> <p>6 Q. And for how long did you speak on each</p> <p>7 of those two times that you spoke?</p> <p>8 A. Ten, 15 minutes.</p> <p>9 Q. Ten, 15 minutes each?</p> <p>10 A. (No audible response.)</p> <p>11 (Court Stenographer clarification.)</p> <p>12 A. Yes.</p> <p>13 Q. Thank you. Did you review any documents</p> <p>14 since the last session of your deposition, related to</p> <p>15 this case?</p> <p>16 A. Yes, I have.</p> <p>17 Q. Which documents?</p> <p>18 A. I've reviewed my expert report, and I've</p> <p>19 also reviewed the Loepky document.</p> <p>20 Q. And since the last session of your</p> <p>21 deposition, have you found any other new documents</p> <p>22 that you claim support your opinions, that you have</p> <p>23 not previously disclosed?</p> <p>24 A. No.</p> <p>25 Q. Dr. Najafi, at the first session of your</p>

<p style="text-align: right;">Page 274</p> <p>1 deposition, you told me that you had mistakenly</p> <p>2 failed to include in your report, or list in</p> <p>3 Materials Considered, certain scientific articles</p> <p>4 that you believe support some of your opinions.</p> <p>5 Correct?</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. That's correct.</p> <p>8 Q. And as I recall, we were specifically</p> <p>9 talking about page 27 to 28 of your report, which was</p> <p>10 marked as Exhibit 7.</p> <p>11 MS. ROSE: Can we bring that up?</p> <p>12 THE VIDEOGRAPHER: I'm sorry, what page</p> <p>13 number?</p> <p>14 MS. ROSE: It's Exhibit 7.</p> <p>15 Okay. And we're going to page 27 at the</p> <p>16 bottom. Perfect.</p> <p>17 Q. There at the very bottom, about four</p> <p>18 lines up, we were talking about your statement that</p> <p>19 during the quenching of sodium azide with sodium</p> <p>20 nitrite during both the TEA and zinc chloride</p> <p>21 processes, there was -- and I'm going to quote</p> <p>22 here -- "a substantial risk during this step that</p> <p>23 nitrous acid is formed, which can nitrosate</p> <p>24 trimethylamine, dimethylamine, and form NDMA, as well</p> <p>25 as nitrosate triethylamine or diethylamine to form</p>	<p style="text-align: right;">Page 276</p> <p>1 MR. NIGH: Form objection.</p> <p>2 A. That is correct.</p> <p>3 Q. [Audio dropout] article by Sun. Is that</p> <p>4 correct?</p> <p>5 (Court Reporter Clarification.)</p> <p>6 MS. ROSE: Oh, I'm sorry.</p> <p>7 I said, after taking a break,</p> <p>8 plaintiffs' counsel provided me with three documents</p> <p>9 that Dr. Najafi claims supported the proposition we</p> <p>10 just read in his report. And the first one was a</p> <p>11 link to a 2010 article by Sun that just included the</p> <p>12 abstract.</p> <p>13 Q. Do you recall that, Dr. Najafi?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. Yes, I do.</p> <p>16 MS. ROSE: Can we put up Tab 57.</p> <p>17 Q. Dr. Najafi, is this the abstract that</p> <p>18 your counsel provided to me during the first session</p> <p>19 of your deposition?</p> <p>20 MR. NIGH: I actually haven't seen it</p> <p>21 come in the documents yet.</p> <p>22 MS. ROSE: Oh, okay.</p> <p>23 A. I cannot see it. You know, if you</p> <p>24 could -- is it on the exhibit portion?</p> <p>25 MR. NIGH: It's not there yet.</p>
<p style="text-align: right;">Page 275</p> <p>1 NDEA. This is a well-established textbook reaction</p> <p>2 that should be recognized by process chemists working</p> <p>3 in the pharmaceutical industry companies" -- sorry --</p> <p>4 "pharmaceutical industry for companies like ZHP."</p> <p>5 Correct?</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. Would you highlight the section that</p> <p>8 you're referring to, because I don't -- I don't see</p> <p>9 it on the screen?</p> <p>10 Q. Sure.</p> <p>11 MS. ROSE: Dan -- right there. I'm</p> <p>12 sorry, Ben. Thanks.</p> <p>13 A. Okay. Let me just -- give me a sec.</p> <p>14 I'm looking at the exhibit in the bigger text to --</p> <p>15 if you'd be kind enough to give me a second so I can</p> <p>16 refresh my memory.</p> <p>17 That's correct.</p> <p>18 Q. Okay. At the time, you agreed that the</p> <p>19 document you cited for that proposition, which is on</p> <p>20 the next page --</p> <p>21 MS. ROSE: We can move to 28. Thank</p> <p>22 you.</p> <p>23 Q. Which is a page of a website about</p> <p>24 sodium azide, did not support the whole passage.</p> <p>25 Correct?</p>	<p style="text-align: right;">Page 277</p> <p>1 Q. It's right up on the Zoom screen. It</p> <p>2 also should be up on the exhibit portion.</p> <p>3 A. Exhibit what?</p> <p>4 Q. Oh, sorry, apologies. It should be</p> <p>5 Exhibit 15. I'll mark it as that.</p> <p>6 A. 15. I don't -- I don't have it yet.</p> <p>7 MR. NIGH: Dan, have you put it in the</p> <p>8 folder? There it is, I see it now.</p> <p>9 Just refresh it again, Dr. Najafi.</p> <p>10 THE WITNESS: Okay.</p> <p>11 A. Okay, I got it. Give me a sec. This</p> <p>12 is -- the title is, "Theoretical Investigation of</p> <p>13 N-Nitrosodimethylamine Formation From Nitrosation of</p> <p>14 Trimethylamine."</p> <p>15 Q. Correct.</p> <p>16 A. Correct. So I'm -- yeah, yes. That</p> <p>17 is -- that is one of the articles. Let me take a</p> <p>18 look at the pathway they're showing here.</p> <p>19 So I am -- I meant not to cite this</p> <p>20 article, per se. Loepky is the one that I would</p> <p>21 have cited since that was in my possession at that</p> <p>22 time.</p> <p>23 This is an article that, you know, my --</p> <p>24 our lawyers pointed out to me. But it also supports</p> <p>25 my, you know, assertion that trimethylamine,</p>

<p style="text-align: right;">Page 278</p> <p>1 triethylamine, tripropylamine, basically any trialkyl 2 amine, can get nitrosated with nitrosonium ions, and 3 undergo the pathway that Sun and -- you know, the 4 authors, Sun, et al., are pointing to. 5 Q. Okay. But you did not read this Sun 6 article prior to forming your opinions in this case? 7 A. No. 8 Q. In addition -- 9 A. However -- let me continue. However, 10 this article further substantiates Loeppky, which is 11 the one that I'm relying on. 12 Q. Okay. In addition to this online 13 abstract for the 2010 Sun article, plaintiffs' 14 counsel also provided me, during your first 15 deposition -- sorry -- first session of this 16 deposition, with a PDF of an article that was marked 17 as having been used at the deposition of Peng Dong. 18 Do you recall that? 19 A. I believe I do. I have not reviewed 20 that, you know, between our last conversation and 21 today. 22 Q. Well, I'll represent that you told me at 23 the first session of your deposition that the 24 plaintiffs' counsel sent this to you -- sorry, sent 25 that article that was used in the Peng Dong</p>	<p style="text-align: right;">Page 280</p> <p>1 Sun et al. from The Journal of Physical Chemistry, 2 previously marked ZHP-211, was received and marked 3 for identification.) 4 A. Okay. 5 Q. Do you see it now? 6 A. No. Oh, yes, I do. 7 Q. Okay. Great. 8 A. Yeah. 9 Q. Do you see that the title is 10 "Theoretical Investigation of N-Nitrosodimethylamine 11 From Nitrosation of Trimethylamine"? 12 A. That's the -- that's the Sun article, 13 yes. 14 Q. Yeah. So would you agree that this is 15 the full article for the last exhibit I just showed 16 you, which was the online abstract for the same 17 article? 18 A. Give me a second. I would have to 19 confirm that by looking at the -- the Exhibit 15, 20 just to make sure it is the same. 21 Q. Well, why don't we go off the record 22 just for a second, and you can look at these two and 23 just confirm whether they're the same? 24 MR. NIGH: No, that's not an appropriate 25 reason to go off the record.</p>
<p style="text-align: right;">Page 279</p> <p>1 deposition; they sent that to you during a break in 2 your deposition. 3 Do you recall that? 4 MR. NIGH: Form objection. 5 A. Yes. 6 Q. And had you seen -- 7 A. Yes, I do. 8 Q. Okay, great. Had you seen that article 9 that was marked as being used at the Peng Dong 10 deposition prior to forming your opinions in this 11 case? 12 A. I had. 13 Q. All right. 14 MS. ROSE: Let's put up Tab 56. 15 I don't think this is it. Sorry, that's 16 my mistake. 58. Here we go. 17 A. This is exhibit number? 18 Q. Oh, sorry, this will be Exhibit 19 Number 16. It should show up -- 20 A. I don't have it. 21 Q. I think Ben is working on putting this 22 into your Exhibit Share. 23 (Exhibit Najafi-16, Article entitled 24 "Theoretical Investigation of N-nitrosodimethylamine 25 Formation from Nitrosation of Trimethylamine," by Zhi</p>	<p style="text-align: right;">Page 281</p> <p>1 MS. ROSE: I -- 2 MR. NIGH: I'm sorry. That's not -- 3 MS. ROSE: The Court has said that if 4 he's reviewing documents, that we can go off the 5 record. 6 MR. NIGH: That's incorrect. That's not 7 what the Court said. It was a whole conversation 8 about how much time they need to review a document; 9 not to compare two documents to see if they're the 10 same document. 11 MS. ROSE: All right. 12 BY MS. ROSE: 13 Q. Dr. Najafi, I will give you a minute or 14 so to look through. One is a one-page document -- 15 A. Okay. 16 Q. -- and it's identical titles and 17 identical dates. 18 A. All right. So let me just double-check 19 that. "Theoretical investigation of N-nitroso 20 formation of dimethylamine" and -- they -- they seem 21 to be -- 22 (Cell phone ringing.) 23 A. Oh, sorry. It's not my doctor, sorry. 24 It's not that. 25 They seem to be the right articles.</p>

<p style="text-align: right;">Page 282</p> <p>1 They, you know, this should be that -- Exhibit 16</p> <p>2 is -- looks -- seems like the full article for the</p> <p>3 abstract you've previously showed me.</p> <p>4 Q. Okay. And you just testified, when we</p> <p>5 looked at the abstract for this article, that you had</p> <p>6 found it for the first time during your last session</p> <p>7 of your deposition. Correct?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 A. I have reviewed hundreds of articles. I</p> <p>10 might have reviewed this as well, but I don't believe</p> <p>11 I've cited this article in my report.</p> <p>12 Q. Okay. But the full Sun article, which</p> <p>13 you said that you had read prior to providing your</p> <p>14 report in this case, did you read that full article</p> <p>15 before forming your opinions, and are you relying on</p> <p>16 it for your opinions?</p> <p>17 MR. NIGH: Form objection, asked and</p> <p>18 answered.</p> <p>19 A. I have not read the full article. I</p> <p>20 scanned through it, and I -- I'm not relying on this</p> <p>21 article for my opinion.</p> <p>22 Q. Okay. All right. Well, let's move on</p> <p>23 to the Loeppky article which you mentioned. So</p> <p>24 that --</p> <p>25 A. Loeppky.</p>	<p style="text-align: right;">Page 284</p> <p>1 Q. Okay.</p> <p>2 MS. ROSE: Okay. Let's pull up the</p> <p>3 Loeppky article. That's going to be Tab 59, and that</p> <p>4 will be exhibit -- I'm going to say 17?</p> <p>5 MR. NIGH: Anita, did you want the full</p> <p>6 article? That's at Tab 60.</p> <p>7 MS. ROSE: Oh, I apologize. Yes, let's</p> <p>8 do Tab 60.</p> <p>9 (Exhibit Najafi-17, Article entitled</p> <p>10 "Ester-Mediated Nitrosamine Formation from Nitrite</p> <p>11 and Secondary or Tertiary Amines," by R.N. Loeppky et</p> <p>12 al., from IARC Scientific Publications, No Bates, 11</p> <p>13 Pages, was received and marked for identification.)</p> <p>14 Q. Okay. So this is a 1984 article</p> <p>15 entitled "Ester-Mediated Nitrosamine Formation from</p> <p>16 Nitrite and Secondary or Tertiary Amines," by</p> <p>17 Loeppky. Is that correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And it's your testimony that you had</p> <p>20 this article in your possession, and read it and</p> <p>21 relied on it prior to drafting your report. Correct?</p> <p>22 A. Yes, I have.</p> <p>23 Q. Dr. Najafi, did ZHP's zinc chloride or</p> <p>24 TEA with quenching manufacturing processes --</p> <p>25 (Court Reporter Clarification.)</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. Oh, I'm sorry, Loeppky. Thank you for</p> <p>2 correcting my pronunciation.</p> <p>3 So the Loeppky article that your counsel</p> <p>4 provided to me during the first session of your</p> <p>5 deposition, that is the only new article that you are</p> <p>6 relying on for the statements set forth in your</p> <p>7 report. Correct?</p> <p>8 A. That is correct. However, my assertion</p> <p>9 that trialkyl amine converts to, effectively, dialkyl</p> <p>10 nitrosamine has also been substantiated by European</p> <p>11 Medical Authority, and I think that's another, you</p> <p>12 know, report that I've cited in my -- in my expert</p> <p>13 report.</p> <p>14 Q. Sure. But I'm just asking, I'm trying</p> <p>15 to clarify. Because three documents were provided to</p> <p>16 me in the last session of deposition as new materials</p> <p>17 that you claim to have reviewed and meant to cite in</p> <p>18 your deposition.</p> <p>19 But just for clarification: The only</p> <p>20 article that you reviewed prior to writing your</p> <p>21 report, and meant to cite in your report but did not,</p> <p>22 was this Loeppky article that your counsel provided</p> <p>23 to me in the last session. Correct?</p> <p>24 MR. NIGH: Form objection.</p> <p>25 A. Yes, that's correct.</p>	<p style="text-align: right;">Page 285</p> <p>1 MS. ROSE: Oh, no problem. I'm not</p> <p>2 reading, just so you know. I'm just a fast talker.</p> <p>3 Q. Did ZHP's zinc chloride or TEA with</p> <p>4 quenching manufacturing processes involve the use of</p> <p>5 ethylene glycol as a solvent?</p> <p>6 A. Let me review the, you know -- that</p> <p>7 process. It's in my expert report.</p> <p>8 Q. Oh?</p> <p>9 A. Just give me a second.</p> <p>10 Q. If you want to look at page 25 of your</p> <p>11 report, which was Exhibit 7.</p> <p>12 A. Yes, I am looking at it as we speak.</p> <p>13 Okay. What is -- and what is your question?</p> <p>14 Q. I was asking if ZHP's zinc chloride or</p> <p>15 TEA with quenching manufacturing processes involved</p> <p>16 the use of ethylene glycol as a solvent?</p> <p>17 A. No, it does not use ethylene glycol.</p> <p>18 But your -- you know, you make your conclusion based</p> <p>19 on the fact that a trialkyl amine transforms to</p> <p>20 dialkyl amine, and then it gets nitrosated. And, you</p> <p>21 know, one, you know, often hypothesizes how a</p> <p>22 chemical gets transformed, often after the fact,</p> <p>23 where you see an impurity like NDEA, and then you try</p> <p>24 to develop a hypothesis and root cause analysis.</p> <p>25 So that has been the conclusion of</p>

<p style="text-align: right;">Page 286</p> <p>1 European Medical Authority, ma'am; and it's also the 2 conclusion of Loeppky, based on my review of Loeppky 3 and others, that trialkyl converts to dialkyl, and 4 then gets nitrosated. 5 To -- you know, to assert that ethylene 6 glycol is not present, I can tell you that there are 7 other ester moieties are present within the ZHP's 8 manufacturing process. And, you know, and that could 9 simply catalyze the process. 10 Q. Okay. So if -- 11 MR. NIGH: And I object to form of the 12 question. 13 MS. ROSE: Okay. 14 Q. I believe the answer at the beginning of 15 that was no, that ethylene glycol is not involved in 16 the manufacturing processes used by ZHP. 17 You also mentioned an ester. Did ZHP's 18 zinc chloride or TEA with quenching processes involve 19 the use of the ester 2-acetoxyethanol? 20 MR. NIGH: Form objection. 21 A. Esters are present in the process of the 22 ZHP transformation. The molecule of valsartan 23 contains that ester. 24 Q. Which ester specifically? 25 A. I would, you know, basically -- do you</p>	<p style="text-align: right;">Page 288</p> <p>1 Q. Okay. And is COOCH₃ that you're 2 identifying, is that -- would that be defined as a 3 high-boiling ester? 4 A. You have -- yeah, it is a high-boiling 5 ester. 6 Q. Does it depend on the temperature at 7 which it is used, whether it's a high-boiling ester? 8 MR. NIGH: Form objection. 9 A. Something is a high-boiling ester, 10 depends on its molecular weight. 11 Q. Okay. Did the zinc chloride or TEA 12 processes involve the use of a nitrous ester? 13 A. No, they do not. 14 Q. Okay. If you look at page 2 of the PDF, 15 which is the fourth full sentence -- 16 MS. ROSE: Sorry, we're going back to 17 Tab 60, which was, I believe, Exhibit 17. 18 Okay. So we're on page 2 of the PDF, 19 fourth full sentence. 20 A. This is Exhibit -- Exhibit -- 21 Q. It's the last exhibit, which I think is 22 17. 23 A. Got it. 17. 24 MR. NIGH: It shows up as Tab 60, on the 25 document.</p>
<p style="text-align: right;">Page 287</p> <p>1 see the -- right above "Purification Step"? Right 2 above the purification step? I don't know if I can 3 point to it. 4 (Simultaneous speaking.) 5 Q. Okay. 6 A. But you have COO -- COO methyl. COOCH₃ 7 is an ester. 8 Q. And is that ester 2-acetoxyethanol? 9 A. It does not have to be. You know, you 10 make -- you make your hypothesis based on the fact 11 that, A, you have this triethylamine impurity; or you 12 have this tri -- you know, essentially, 13 diethylamine -- nitrosodimethyl -- diethylamine 14 present. And then you look back and see you have 15 triethylamine; it's a logical conclusion. 16 So that's my expert opinion, and it's 17 also the expert opinion of the authors of European 18 Medical Authority document, as well as the Loeppky 19 and others. 20 Q. Okay. But my specific question was: 21 You just said COOCH₃ was an ester. I'm just asking: 22 Is that 2-acetoxy -- sorry -- 2-acetoxyethanol? 23 That's the only question I'm asking, because I don't 24 know, I'm not a chemist. 25 A. No. No, it is not.</p>	<p style="text-align: right;">Page 289</p> <p>1 Q. Tab 60. 2 MR. NIGH: Yeah. 3 A. Okay. 4 Q. It says, "In the course of verifying 5 this hypothesis, we have investigated that reaction 6 of secondary amines with the acetate esters of 7 ethylene glycol, and sodium nitrite and ethylene 8 glycol. These experiments have been performed to 9 answer the question: Can esters and ionic nitrite 10 lead to extensive nitrosation of secondary and 11 tertiary amines? The results presented in this paper 12 demonstrate that the answer is yes. Moreover, we 13 believe that this general reaction scheme is mainly 14 responsible for the production of N-nitrosamines in 15 cosmetics, metal-working fluids, shampoos and other 16 toiletry articles, as well as certain cooked and 17 cured meats." Correct? 18 A. I am reading that statement. 19 Okay. And what is your question 20 regarding this statement? 21 Q. This statement states that the point of 22 the article is to evaluate the role of esters and 23 ionic nitrite in the formation of nitrosamines. 24 Correct? 25 MR. NIGH: Form objection.</p>

<p style="text-align: right;">Page 290</p> <p>1 A. Yes, it -- it confirms that</p> <p>2 triethylamine or trimethylamine in the presence of</p> <p>3 sodium nitrite and ethylene glycol, or their</p> <p>4 corresponding ethylene glycol esters, could transform</p> <p>5 into, you know, nitrosamines.</p> <p>6 Q. Do you know if any of the experiments</p> <p>7 described in these papers involved a reaction that</p> <p>8 did not include ethylene glycol specifically?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. Please repeat your question.</p> <p>11 Q. You said that this talked about the</p> <p>12 reaction of sodium nitrite in ethylene glycol or an</p> <p>13 ethylene glycol equivalent. But I'm just asking you</p> <p>14 to confirm that all of the experiments described in</p> <p>15 these papers did use ethylene glycol, not some other</p> <p>16 equivalent?</p> <p>17 MR. NIGH: Form objection.</p> <p>18 A. I have not gone thoroughly through the</p> <p>19 paper. I can, if you wish me -- if you wish, I would</p> <p>20 go through the entire paper. However, you know, in</p> <p>21 chemistry, and in conducting root cause analysis,</p> <p>22 which is really what we're doing here, is we have a</p> <p>23 genotoxic impurity like tri -- like NDEA, and we're</p> <p>24 trying to figure out where it came from.</p> <p>25 In the course of my investigation,</p>	<p style="text-align: right;">Page 292</p> <p>1 I'm sorry, you're on Figure 3, I need to go to</p> <p>2 Table 1. Thank you.</p> <p>3 Q. Are you there, Dr. Najafi?</p> <p>4 Table 1 here is a chart entitled,</p> <p>5 "Ester-Mediated Nitrosation of Secondary Amines."</p> <p>6 Correct?</p> <p>7 A. Yes.</p> <p>8 Q. And dimethylamine, the secondary amine</p> <p>9 that you say is necessary to form NDMA in the zinc</p> <p>10 chloride proces, is not one of the secondary amines</p> <p>11 that were tested. Correct?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. The answer is "correct." However, in --</p> <p>14 when you are, again, trying to figure out the root</p> <p>15 cause, and do a root cause analysis of a genotoxic</p> <p>16 impurity, you rely on other transformations.</p> <p>17 Essentially, you say, if one plus one equals two,</p> <p>18 therefore -- and therefore, one plus two will be</p> <p>19 equals three. So, you know, you -- you know, it's</p> <p>20 very much translatable. It's very much in chemical</p> <p>21 reactions, it's -- you often rely. If trimethylamine</p> <p>22 converts to NDMA, triethylamine will convert to NDEA.</p> <p>23 And tripropylamine, we may not have any</p> <p>24 evidence for tripropylamine. But because</p> <p>25 trimethylamine converts, therefore tripropyl will</p>
<p style="text-align: right;">Page 291</p> <p>1 looking at this trans -- chemical transformation,</p> <p>2 it -- the ethylene glycol can be, you know,</p> <p>3 potentially an alcohol. And we have plenty of that</p> <p>4 in the -- you know, in the -- in ZHP's</p> <p>5 transformation. There are esters that are present in</p> <p>6 the ZHP transformation.</p> <p>7 And there are lots of other evidences</p> <p>8 from -- and statements from other investigators and</p> <p>9 other chemists, who have speculated that</p> <p>10 triethylamine converts to NDEA. So that's my</p> <p>11 assertion; that's my opinion. And I believe the</p> <p>12 source of NDEA is triethylamine.</p> <p>13 Q. Okay. Again, I was not asking that</p> <p>14 question; I was really just asking about the use of</p> <p>15 ethylene glycol in this article. But I'll accept</p> <p>16 your answer that you, off the top of your head, don't</p> <p>17 know, and the article speaks for itself.</p> <p>18 A. Yeah.</p> <p>19 MS. ROSE: If we can look at page 357 of</p> <p>20 this document, as noted in the top right-hand corner.</p> <p>21 It's page 5 of the PDF.</p> <p>22 Q. Can you see that on your paper?</p> <p>23 MR. NIGH: Form objection to the</p> <p>24 colloquy before this.</p> <p>25 MS. ROSE: It's Table 1. It's Table 1.</p>	<p style="text-align: right;">Page 293</p> <p>1 too. It's -- it is very well understood in chemistry</p> <p>2 for the last probably three, four hundred years.</p> <p>3 Q. Okay. Dr. Najafi, when did you first</p> <p>4 personally become aware that dimethylamine, in the</p> <p>5 presence of sodium nitrite, could result in the</p> <p>6 formation of NDMA?</p> <p>7 MR. NIGH: Form objection.</p> <p>8 A. When did I personally -- your question</p> <p>9 again, when did I personally became aware that</p> <p>10 dimethylamine converts to NDMA?</p> <p>11 Q. Yes.</p> <p>12 A. I cannot recall. You know, I have been</p> <p>13 aware of nitrosamines since the late 1970s, and I</p> <p>14 have been engaged in the chemistry of nitrosamines.</p> <p>15 I had an interest in essentially avoiding sodium</p> <p>16 nitrite, in -- that are associated with curing the</p> <p>17 meat. So I have been aware of NDMA. I cannot recall</p> <p>18 exactly when I became aware of it, what year it was,</p> <p>19 and what time it was.</p> <p>20 Q. Okay. But I wasn't asking when you</p> <p>21 become aware of NDMA, but when did you first become</p> <p>22 aware of the process by which dimethylamine, in the</p> <p>23 presence of sodium nitrite, that then converts to</p> <p>24 nitrous acid, that then converts to a nitrosonium</p> <p>25 ion, can result in the formation of NDMA? When did</p>

<p style="text-align: right;">Page 294</p> <p>1 that reaction become known to you?</p> <p>2 MR. NIGH: Form objection.</p> <p>3 A. Probably 20-some years ago.</p> <p>4 Q. And when did you first read this Loeppky</p> <p>5 article we've been discussing?</p> <p>6 A. I have become aware of Loeppky article</p> <p>7 probably over the last 12 months, I would say,</p> <p>8 probably 12 months ago, maybe -- maybe more, as we</p> <p>9 were investigating presence of NDMA in various drug</p> <p>10 APIs.</p> <p>11 Q. So you became aware of the Loeppky</p> <p>12 article after you were retained as an expert in</p> <p>13 litigation relating to valsartan?</p> <p>14 MR. NIGH: Form objection.</p> <p>15 A. That's correct.</p> <p>16 Q. Okay.</p> <p>17 MS. ROSE: I'd like to take a break for</p> <p>18 a couple of minutes. Where are we, 8:45? Remind me</p> <p>19 again -- we can go off the record. Remind me again.</p> <p>20 THE VIDEOGRAPHER: Going off the video</p> <p>21 record, the time is 8:46.</p> <p>22 (A brief recess takes place.)</p> <p>23 THE VIDEOGRAPHER: We are back on the</p> <p>24 video record. The time is 9:03 a.m., and this begins</p> <p>25 Media Unit Number 2.</p>	<p style="text-align: right;">Page 296</p> <p>1 Teva and Torrent. Correct?</p> <p>2 A. That's correct.</p> <p>3 Q. And largely, I'm interested in finding</p> <p>4 out if you have an intent to offer opinions with</p> <p>5 regard to the finished dose manufacturers, and</p> <p>6 specifically, their conduct in this case. Okay?</p> <p>7 A. Yes.</p> <p>8 Q. You have a copy of your expert report</p> <p>9 with you; I believe it was previously introduced as</p> <p>10 Exhibit 7.</p> <p>11 A. Correct.</p> <p>12 Q. Can you take a look at page 11 of your</p> <p>13 expert report? Let me know when you have that</p> <p>14 available.</p> <p>15 A. I have page 11 on the PDF.</p> <p>16 Q. Please look at page 11 on the numbering</p> <p>17 in your report. So it will be small 11 at the</p> <p>18 bottom; I believe it's page 13 of the PDF.</p> <p>19 A. That's exactly right, I have that.</p> <p>20 Q. And take a look at the top paragraph of</p> <p>21 that section for me. And specifically, I'm</p> <p>22 interested in the sentence about halfway down that</p> <p>23 starts, "Finished dose manufacturers reference the</p> <p>24 DMFs."</p> <p>25 Do you see that?</p>
<p style="text-align: right;">Page 295</p> <p>1 MS. ROSE: I'm going to turn the</p> <p>2 questioning over now to counsel for Teva.</p> <p>3 EXAMINATION BY MR. HARKINS:</p> <p>4 Q. Good morning, Dr. Najafi. Can you hear</p> <p>5 me okay?</p> <p>6 A. Good morning, Steven. Yes, I can hear</p> <p>7 you fine.</p> <p>8 Q. Good. Well, I'm glad to say we got to</p> <p>9 meet already. And you understand that I'm counsel</p> <p>10 for the Teva defendants, one of the finished dose</p> <p>11 manufacturers in this case. Correct?</p> <p>12 A. I understand.</p> <p>13 Q. All right. And obviously, we'll just be</p> <p>14 proceeding with some questioning on that.</p> <p>15 I understand that you also have a call</p> <p>16 in approximately 30 minutes that you're going to take</p> <p>17 a break for. Is that right?</p> <p>18 A. That's correct.</p> <p>19 Q. All right. Just let me know if that</p> <p>20 call comes in, and we'll figure out how to pause the</p> <p>21 questioning. Okay?</p> <p>22 A. That will be great, thank you.</p> <p>23 Q. All right. Dr. Najafi, my questions are</p> <p>24 going to be focused on the finished dose</p> <p>25 manufacturers in the case, who you understand are</p>	<p style="text-align: right;">Page 297</p> <p>1 A. I'm reading -- hang on a second. So I</p> <p>2 am -- yes, "finished dose" -- okay, I need to read</p> <p>3 the whole paragraph, Steven. Just give me a second.</p> <p>4 Q. Are you finished?</p> <p>5 A. Yes, I am.</p> <p>6 Q. My question, Dr. Najafi, is: You are</p> <p>7 familiar with the process by which finished dose</p> <p>8 manufacturers reference a DMF in their ANDA.</p> <p>9 Correct?</p> <p>10 A. Yes, I am.</p> <p>11 Q. And that allows a finished dose</p> <p>12 manufacturer to incorporate API that's been</p> <p>13 manufactured by another company into their finished</p> <p>14 drug -- finished drug product. Correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And that DMF may contain proprietary</p> <p>17 commercial processes that are not known to the</p> <p>18 finished drug manufacturer, but they are allowed to</p> <p>19 incorporate those by reference to the DMF. Correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Dr. Najafi, last week during your</p> <p>22 testimony, you were asked if it was your opinion that</p> <p>23 as of 2013, finished dose manufacturers who looked at</p> <p>24 the TEA-with-quenching process should have known that</p> <p>25 it was going to result in the production of NDEA.</p>

<p style="text-align: right;">Page 298</p> <p>1 And your answer to that question was:</p> <p>2 "Finished dose manufacturers, if they had access to</p> <p>3 the DMF, they should have -- you know, they should</p> <p>4 have been aware of the chemical process."</p> <p>5 Do you recall that testimony?</p> <p>6 MR. NIGH: Form objection.</p> <p>7 A. I do.</p> <p>8 Q. My question, Dr. Najafi: Have you</p> <p>9 reviewed documents to determine what information from</p> <p>10 ZHP's DMF on the process was available and known to</p> <p>11 the finished dose manufacturers, specifically Teva?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. Steven, I do not know what documents</p> <p>14 Teva has reviewed as it relates to ZHP's Drug Master</p> <p>15 File. But, you know, there's no question that, you</p> <p>16 know, that the finished dose manufacturer is</p> <p>17 responsible for evaluating the API. If they have</p> <p>18 access to the chemical routes of synthesis, then</p> <p>19 obviously, they need to do risk analysis. If they</p> <p>20 don't have access to it, then they need to thoroughly</p> <p>21 test the API, and do what we -- what I call</p> <p>22 untargeted analysis, similar to what Novartis did.</p> <p>23 And Novartis, in this case, is a</p> <p>24 finished dose manufacturer, just like Teva. And do</p> <p>25 their due diligence with the API, do an identity</p>	<p style="text-align: right;">Page 300</p> <p>1 Q. Great.</p> <p>2 Your opinion that a reasonable chemist</p> <p>3 from the finished dose manufacturers would have</p> <p>4 identified the potential for nitrosamines to form</p> <p>5 assumes that the finished dose manufacturers had</p> <p>6 access to chemical -- the information on ZHP's</p> <p>7 process. Correct?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 A. If they had access to ZHP's process,</p> <p>10 then they could have conducted a root cause analysis.</p> <p>11 So the answer is yes.</p> <p>12 Q. And if they did not have access to it,</p> <p>13 they would not have been able to conduct that</p> <p>14 analysis, naturally. Correct?</p> <p>15 MR. NIGH: Form objection.</p> <p>16 Q. And my question is just with regard to</p> <p>17 that analysis; not another analysis, just that</p> <p>18 analysis, that root cause analysis that you</p> <p>19 described. If they did not have access to it, then</p> <p>20 naturally, they wouldn't have been able to conduct</p> <p>21 it. Right?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A. So it's really not root cause analysis;</p> <p>24 it's really risk analysis. So if they had access to</p> <p>25 the routes of synthesis, the chemical -- the chemical</p>
<p style="text-align: right;">Page 299</p> <p>1 test; conduct a residual solvent analysis, which is</p> <p>2 prescribed by the various regulatory authorities; the</p> <p>3 USP, you know, FDA, EMA; everybody prescribes what</p> <p>4 they need to do, in order to make sure that their</p> <p>5 finished dose does not contain any of the Class 1 or</p> <p>6 genotoxic impurities or solvent impurities. And, you</p> <p>7 know, that would be, you know, the responsibility of</p> <p>8 your client.</p> <p>9 In addition, they would need to have a</p> <p>10 quality agreement in place, and also conduct a</p> <p>11 thorough quality check inspection of the API</p> <p>12 manufacturer.</p> <p>13 Q. Dr. Najafi, I'm not asking generally</p> <p>14 about what your opinion is, as to what the finished</p> <p>15 dose manufacturers should have done. I understand</p> <p>16 that from your report.</p> <p>17 My question is: You have not analyzed</p> <p>18 or reviewed documents to determine what information</p> <p>19 on ZHP's chemical processes was actually available to</p> <p>20 the finished dose manufacturers when they submitted</p> <p>21 their ANDAs. Correct?</p> <p>22 MR. NIGH: Form objection.</p> <p>23 A. I do not know whether your client, Teva,</p> <p>24 has reviewed any material -- any -- what they</p> <p>25 reviewed, as it relates to ZHP's DMF.</p>	<p style="text-align: right;">Page 301</p> <p>1 synthesis, then they could conduct risk analysis of</p> <p>2 various reagents that are present.</p> <p>3 And there must have been something in</p> <p>4 the ANDA that says the route of synthesis was</p> <p>5 changed, so they must have been aware that the</p> <p>6 synthetic route has been modified by ZHP, and they</p> <p>7 could have further investigated that.</p> <p>8 So there is the -- there is the upfront</p> <p>9 risk analysis, and then there is the back-end</p> <p>10 analysis of the API that your clients should have</p> <p>11 conducted.</p> <p>12 Q. Dr. Najafi, I'm talking just</p> <p>13 specifically with respect to the analysis that you</p> <p>14 testified an organic chemist would have been able to</p> <p>15 perform, with access to information about the</p> <p>16 process. If they did not have information about that</p> <p>17 process, they would not have been able to conduct any</p> <p>18 type of analysis, the analysis that you just</p> <p>19 described. Right?</p> <p>20 MR. NIGH: Form objection.</p> <p>21 A. If the chemists at Teva did not have</p> <p>22 access to routes of synthesis, then obviously they</p> <p>23 could not have conducted a risk analysis. However,</p> <p>24 there were indications that ZHP changed the process,</p> <p>25 and they have -- and, you know, and there was</p>

<p style="text-align: right;">Page 302</p> <p>1 various, you know, information that -- in the DMF 2 that the process was changed, you know, and various 3 solvents were changed and so forth. 4 So there were some indication that 5 things are not the same as the brand product. 6 Q. Dr. Najafi, there is no requirement that 7 a finished dose manufacturer have access to the 8 closed portion of another company's DMF in order to 9 manufacture drug products under an ANDA that 10 references that DMF. Correct? 11 MR. NIGH: Form objection. 12 A. Could you repeat your question? 13 Q. Sure. There is no requirement for a 14 finished dose manufacturer to have access to the 15 closed portion of another company's DMF, in order to 16 manufacture drug products under an ANDA that 17 references that DMF. Correct? 18 MR. NIGH: Form objection. 19 A. That is correct -- that is correct. 20 However, as I mentioned, the drug substance 21 manufacturer should have notified the finished dose 22 manufacturer of the changes to the DMF. 23 Q. Understood. 24 I'd like to turn to another area of your 25 report, Dr. Najafi. If you could go to page 36. And</p>	<p style="text-align: right;">Page 304</p> <p>1 paragraph. Take a moment if you want to refresh on 2 that. 3 MR. NIGH: Form objection. 4 A. Okay. 5 Q. Dr. Najafi, neither of the finished dose 6 manufacturers, Teva or Torrent, are identified by 7 name in this section of your report. Correct? 8 A. That's correct. 9 Q. And there are no citations, either in a 10 footnote or in the body of the report, to any 11 documents in this section of your report. Correct? 12 A. That's correct. 13 Q. I understand your opinions with respect 14 to what a finished dose manufacturer should do in 15 these areas, as you stated already today. Have 16 you -- strike that. 17 Do you intend to offer opinions on the 18 adequacy of the supplier qualification process 19 performed by the specific finished dose manufacturers 20 in this case with respect to ZHP? Have you formed 21 those opinions? 22 MR. NIGH: Form objection. 23 A. Based on -- yes, I have. So based on 24 the fact that they obviously incorporated the ZHP's 25 API in their final drug and marketed it, it was</p>
<p style="text-align: right;">Page 303</p> <p>1 that is 36 on your report, which I'll confirm, I 2 believe will be page 38 on the PDF. 3 A. Okay. 4 Q. Let me know when you're there. 5 A. Page 38 of the PDF. 6 Q. Do you see the heading "Qualification of 7 a Drug Substance (API) Supplier by a Finished Dose 8 Manufacturer"? 9 A. No, I don't. Hang on one second. I 10 think you're on page 36 of the PDF. Okay, hang on. 11 Q. It's the section showing on the screen 12 share. Again, it's definitely 36 on the small page 13 on the bottom of your report. I believe it's page 38 14 of the PDF you're looking at. 15 A. Right. I'm looking at it. 16 "Qualification of a Drug Substance (API) Supplier by 17 a Finished Dose -- Finished Drug Product 18 Manufacturer." 19 Q. And Dr. Najafi, I understand, and I 20 think this paragraph covers a lot of what you talked 21 about in response to one of my earlier questions, 22 about what you believe are the obligations of a 23 finished dose manufacturer as far as qualifying an 24 API, validating a supplier, and having a quality 25 agreement; I believe are all covered in this</p>	<p style="text-align: right;">Page 305</p> <p>1 obvious that they had not done comparable due 2 diligence as Novartis, which is another finished dose 3 manufacturer in this case. 4 And they basically must have relied on 5 ZHP's certificate of analysis, and -- or they may not 6 have done sufficient due diligence, you know, to 7 qualify the API. 8 So that is an opinion that I've actually 9 expressed in various parts of my report, and I'm 10 expressing right now. 11 Q. Dr. Najafi, you did not review the 12 actual supplier qualification documents from Teva and 13 Torrent to form this opinion; you are assuming that 14 this process was deficient because whatever they did, 15 it did not identify the potential for nitrosamines to 16 form during ZHP's manufacturing process. Is that 17 fair? 18 MR. NIGH: Form objection. 19 A. That is correct. My opinion is 20 primarily based on the fact that they allowed this 21 genotoxic impurity in their finished product and they 22 marketed it, and -- as opposed to Novartis, who ran a 23 very simple GC-FID and saw a very -- very messy 24 chromatogram, you know, in comparison to ZHP's own 25 certificate of analysis, and they said, this doesn't</p>

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1 jive and we need to do further investigation.
 2 I think my opinion is that ZHP -- your
 3 client simply rushed and they took -- they took the
 4 risk. Essentially, they accepted the risk and they
 5 moved forward.
 6 Q. And just to confirm: When you say
 7 "rushed" or "accepted the risk," that is based on
 8 what you are assuming, based on the fact they failed
 9 to identify the impurity; not your independent review
 10 of the supplier qualification documents for Teva.
 11 Right?
 12 A. Yes.
 13 Q. So a similar question, and I just want
 14 to make sure I understand where you do and don't have
 15 opinions. Did you evaluate the finished dose
 16 manufacturers' quality policies for adequacy?
 17 MR. NIGH: Form objection.
 18 A. I don't believe so.
 19 Q. Did you evaluate and form opinions on
 20 the adequacy of the finished dose manufacturers'
 21 quality management systems?
 22 A. I don't believe I had access to those
 23 documents.
 24 Q. And then at the end of your paragraph,
 25 you refer to quality agreements. Did you review the

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1 finished dose manufacturers' quality agreements with
 2 ZHP, and form opinions on the adequacy of those
 3 agreements?
 4 A. I don't believe that the quality
 5 agreements were provided to me. But again, I'm
 6 simply looking at the final, you know, act, which is
 7 incorporating this, you know, sort of adulterated API
 8 in their finished -- you know, finished product.
 9 And, you know, the outcome is, obviously, they didn't
 10 do sufficient due diligence.
 11 Q. I understand, Dr. Najafi.
 12 And then the final thing I just want to
 13 confirm: You have a reference in here, about
 14 two-thirds of the way down the paragraph, to: "In
 15 addition to the documentation, the qualification
 16 process should include testing of API batches."
 17 Do you see that?
 18 A. Would you highlight that? And -- okay.
 19 Yes.
 20 Q. Did you review and evaluate any of the
 21 chromatography testing results for the API that Teva
 22 performed?
 23 A. I don't believe I have.
 24 Q. And generally speaking, just for those
 25 areas where you did not review documents, is it fair

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1 to say you have not formed opinions that you intend
 2 to offer on the adequacy of those specific areas?
 3 MR. NIGH: Form objection.
 4 A. While I have not reviewed any
 5 chromatography testing that Teva or Torrent might
 6 have done, the end result is, even if they had done
 7 it, they did not do sufficient due diligence. And
 8 they might not have done it.
 9 Q. But you -- just to clarify, you've not
 10 reviewed documents to know, one way or another,
 11 whether they did it, or whether the specific testing
 12 was appropriate or accurate. Correct?
 13 MR. NIGH: Form objection.
 14 A. I think -- I think I already answered
 15 the question.
 16 Q. You may have. Is the answer yes?
 17 MR. NIGH: Objection to form.
 18 A. As I said, I have not seen any
 19 chromatograms from Teva and Torrent, so -- I don't
 20 believe I have seen anything. However, based on the
 21 fact that their finished dose -- their finished
 22 product contained the NDMA and they allowed it, so
 23 it's obvious that they didn't do sufficient due
 24 diligence and sufficient analysis of the API.
 25 Q. And Dr. Najafi, I understand your

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1 opinion with respect to the due diligence. I'm
 2 asking specifically with regards to the
 3 chromatography testing.
 4 And I want to just confirm: You have
 5 not reviewed any of the results of the finished dose
 6 manufacturers' chromatography testing to determine if
 7 the testing itself -- unrelated to supplier
 8 qualification -- if the testing itself was
 9 appropriate or accurate, have you?
 10 MR. NIGH: Objection, asked and answered
 11 multiple times.
 12 A. They were not provided to me, but I'm
 13 happy to review them if you have them in front of
 14 you.
 15 Q. No need, Dr. Najafi.
 16 And I think -- let me see -- one
 17 question, I guess, before we may go on our break
 18 here. You have not seen any evidence that Teva was
 19 aware of the potential for nitrosamine formation in
 20 valsartan API or valsartan drug products prior to
 21 June 2018, have you?
 22 MR. NIGH: Form objection.
 23 A. I don't believe I have seen anything
 24 pointing to Teva knowing that there's NDMA in the
 25 valsartan API. However -- however -- so I answered

<p style="text-align: right;">Page 310</p> <p>1 your question. However, the quality -- the QA 2 inspection by Teva, and the quality agreement, should 3 have pointed to potential complaints regarding 4 impurities pre-2018. And those -- those should have 5 raised their -- sort of doubt about the quality of 6 API.</p> <p>7 MR. HARKINS: Thank you, Dr. Najafi. 8 Can we go off the record for a moment? 9 THE VIDEOGRAPHER: Yes. 10 We're going off the video record. The 11 time is 9:29 a.m. 12 (A brief recess takes place.) 13 THE VIDEOGRAPHER: We are back on the 14 video record. The time is 9:51 a.m. This begins 15 Media Unit Number 3. 16 BY MR. HARKINS: 17 Q. Dr. Najafi, during the first day of your 18 deposition last week, you were asked when Emery 19 Pharma's next FDA inspection was going to be 20 scheduled for. And you answered, "It could be today, 21 nobody knows. It's a surprise audit." 22 Do you recall that testimony? 23 MR. NIGH: Form objection. 24 A. Yes, I do. 25 Q. You aren't always able to prepare for a</p>	<p style="text-align: right;">Page 312</p> <p>1 A. Do you have anything you want to show 2 me, like a, you know, impurity profile, chromatogram? 3 What are you pointing at? Are you pointing at API 4 identity impurities, as it relates to API? Or are 5 you pointing to impurities as it relates to residual 6 solvents? 7 Q. I'm referring to impurities, not with 8 respect to residual solvents; the impurity standards 9 with regard to the API. Does that help clarify the 10 question? 11 MR. NIGH: Form objection. 12 A. I think you're referring to -- 13 impurities as it relates to API, you're referring to 14 USP-related impurities. 15 Q. Have you reviewed the unidentified 16 impurity standards set out in the ANDAs for the 17 finished dose product in this case? 18 MR. NIGH: Form objection. 19 A. I might have. 20 Q. But you're not familiar with them, off 21 the top of your head, without seeing a document? 22 MR. NIGH: Form objection. 23 A. You know, you need to show me a 24 document. 25 Q. Dr. Najafi, what's a reporting</p>
<p style="text-align: right;">Page 311</p> <p>1 FDA audit in advance. Correct? 2 MR. NIGH: Form objection. 3 A. You know, are you asking me on the -- on 4 the Emery side, or on the -- say, a manufacturer? 5 Q. In your experience working at Emery 6 Pharma, as you testified, it could be a surprise 7 audit. Is it your experience that FDA does not 8 always schedule its audits in advance? 9 MR. NIGH: Form objection. 10 A. They do not always schedule their audits 11 in advance. 12 Q. And when they perform an audit, do they 13 always inform you what products or systems are going 14 to be subject to the audit in advance? 15 MR. NIGH: Form objection. 16 A. I can only -- only speak from my 17 experience. And no, they may just come and do a -- 18 want to do a general audit. They may point to a 19 specific product that they want to focus on. So it's 20 really entirely up to them. 21 Q. Switching gears a little bit. 22 You're familiar, during your review for 23 this case, with the unidentified impurity standards 24 that are contained in the approved ANDAs for the 25 finished dose manufacturers, aren't you?</p>	<p style="text-align: right;">Page 313</p> <p>1 threshold? 2 MR. NIGH: Form objection. 3 A. A reporting threshold, as it relates to 4 any impurities, essentially non-genotoxic impurities, 5 is around 0.1, 0.1 percent. However, for genotoxic 6 impurities, there are no reporting thresholds. 7 Q. And Dr. Najafi, my question may have 8 been confusing. I'm not asking what the specific 9 reporting threshold is. I'm asking, what is a 10 reporting threshold? What does that delineate as far 11 as what a manufacturer is required to do if they see 12 a result above or below that threshold? 13 MR. NIGH: Form objection. 14 A. Do you have anything you want to show 15 me, point to me? 16 Q. Are you not familiar with how a 17 reporting threshold operates, with respect to drug 18 substances? 19 MR. NIGH: Form objection. 20 A. You have to define to me what that 21 means. 22 Q. Assuming that a reporting threshold for 23 a given drug substance is .05, I'll ask you to assume 24 that for purposes of this question. Assuming that -- 25 (Simultaneous speaking.)</p>

<p style="text-align: right;">Page 314</p> <p>1 (Court Stenographer clarification.)</p> <p>2 Q. And I apologize; this may be a long</p> <p>3 question, but just let me finish it for you,</p> <p>4 Dr. Najafi.</p> <p>5 Assuming that a reporting threshold for</p> <p>6 a drug substance is set at 0.05 for purposes of this</p> <p>7 question, what does that require the drug substance</p> <p>8 or finished dose manufacturer testing that drug</p> <p>9 substance to do with respect to unidentified</p> <p>10 impurities?</p> <p>11 MR. NIGH: Form objection.</p> <p>12 A. I'm assuming you're talking -- when you</p> <p>13 say 0.05, you're talking about 0.05 percent?</p> <p>14 Q. Yes, you're -- yes, Doctor, that's</p> <p>15 correct. Apologies.</p> <p>16 A. So assuming their reporting threshold is</p> <p>17 0.05 percent, if they see impurities that fall below</p> <p>18 0.05 percent, batch after batch, they have the duty</p> <p>19 to investigate it. And in this case, not call an</p> <p>20 impurity -- it could be 0.0001 percent. If they can</p> <p>21 see it, and it shows, baseline to baseline, there is</p> <p>22 an impurity, they need to identify it. They need to</p> <p>23 point to it, and, you know, figure out what it is.</p> <p>24 Because it could be a genotoxic agent.</p> <p>25 And if it is a genotoxic agent, then they need to</p>	<p style="text-align: right;">Page 316</p> <p>1 You can answer.</p> <p>2 A. So if a finished dose manufacturer or</p> <p>3 API manufacturer sees an impurity that is below the</p> <p>4 reporting threshold, 0.05 percent, let's assume, and</p> <p>5 they see this impurity repeatedly, and it is,</p> <p>6 obviously, a recent impurity in there, they should --</p> <p>7 they don't have to -- they may not have to report it,</p> <p>8 but they must investigate it.</p> <p>9 And if it is -- let's say, if it's a</p> <p>10 harmless solvent, and it's, you know, it's not --</p> <p>11 they don't need to report it. But if it's a</p> <p>12 genotoxin, then they must report it, and they must</p> <p>13 control it, and, you know, put some guardrail around</p> <p>14 that impurity.</p> <p>15 Q. And Dr. Najafi, just to confirm from</p> <p>16 your testimony before the break: You did not review</p> <p>17 the results of the chromatograms performed by either</p> <p>18 of the finished dose manufacturers to determine what,</p> <p>19 if any, levels of unidentified impurities they were</p> <p>20 seeing in ZHP's API. Correct?</p> <p>21 MR. NIGH: Form objection, asked and</p> <p>22 answered.</p> <p>23 A. As I mentioned before, I did not review</p> <p>24 ZHP [sic] and Torrent's chromatogram. But if you</p> <p>25 have it in your -- in front of you, please feel free</p>
<p style="text-align: right;">Page 315</p> <p>1 control it, they need to figure out why it's being</p> <p>2 generated, you know. And if it's a very high-level</p> <p>3 genotoxin, you know, then they need to obviously, you</p> <p>4 know, dispose of those batches, and, you know, do</p> <p>5 whatever they need to do: Report it to the agency.</p> <p>6 So that's what, you know, a</p> <p>7 manufacturer, whether it's -- you know, the API</p> <p>8 manufacturer or finished dose manufacturer, that's</p> <p>9 what they need to do. And that's what exactly</p> <p>10 Novartis did. So we're not creating some</p> <p>11 hypothetical situation here. Novartis is a finished</p> <p>12 dose manufacturer, just like ZHP -- just like Teva</p> <p>13 and Torrent. And Novartis did the right thing and</p> <p>14 pointed those impurities -- and pointed at those</p> <p>15 impurities, and wanted to figure out what they are.</p> <p>16 Q. But Dr. Najafi, I just want to make sure</p> <p>17 that I understand your opinion before we move on.</p> <p>18 It's your expert opinion in this case</p> <p>19 that a finished dose manufacturer, observing a level</p> <p>20 of unidentified impurity below the reporting</p> <p>21 threshold, is required not only to report, but also</p> <p>22 to identify the substance that is causing that peak,</p> <p>23 regardless of size?</p> <p>24 MR. NIGH: Form objection,</p> <p>25 mischaracterizes his testimony.</p>	<p style="text-align: right;">Page 317</p> <p>1 to share it with me, and I'll be happy to give you my</p> <p>2 opinion.</p> <p>3 Q. Dr. Najafi, I'd like to turn to page 6</p> <p>4 of your report to help you with this next question.</p> <p>5 That's going to be -- I apologize, I may have gotten</p> <p>6 the number wrong. Page 6, and it will be page 8 of</p> <p>7 the PDF. Let me know when you're there.</p> <p>8 A. Six, yes.</p> <p>9 Q. And looking at the bottom paragraph on</p> <p>10 page 6, you reference "a single 320-milligram</p> <p>11 valsartan tablet."</p> <p>12 That's the highest daily dose you've</p> <p>13 identified for any valsartan tablet involved in this</p> <p>14 case. Correct?</p> <p>15 A. Please allow me to read the paragraph</p> <p>16 quickly.</p> <p>17 Yes, I read it.</p> <p>18 Q. And just to confirm -- hopefully, it</p> <p>19 would help to read your report -- 320 milligrams is</p> <p>20 the highest daily dose of valsartan that you're aware</p> <p>21 of. Correct?</p> <p>22 A. Correct.</p> <p>23 Q. Go to the next page of your report,</p> <p>24 seven.</p> <p>25 A. Okay.</p>

<p style="text-align: right;">Page 318</p> <p>1 Q. And I'm suspecting you're going to want</p> <p>2 to read through these paragraphs that finish this</p> <p>3 section.</p> <p>4 My question is going to be: Is the</p> <p>5 240.1 PPM number, identified in the second full</p> <p>6 paragraph on this page, the highest level of NDMA</p> <p>7 that you have identified reported in valsartan API?</p> <p>8 A. Let me -- let me review the -- okay.</p> <p>9 So what is your question?</p> <p>10 Q. Based on the paragraph that you just</p> <p>11 reviewed, is 240.1 parts per million the highest</p> <p>12 level of reported NDMA impurities present in</p> <p>13 valsartan API that you're aware of?</p> <p>14 A. This is in the previous paragraph?</p> <p>15 MR. NIGH: Form objection.</p> <p>16 Q. Sorry, the continued section, that</p> <p>17 starts at the top of page 7 --</p> <p>18 A. Right.</p> <p>19 Q. There's a broken paragraph, and then two</p> <p>20 full paragraphs.</p> <p>21 A. Right. Okay.</p> <p>22 Q. The bottom of the second paragraph --</p> <p>23 A. Point-two --</p> <p>24 Q. Right.</p> <p>25 A. Could you point to that number of</p>	<p style="text-align: right;">Page 320</p> <p>1 you know, pills with more parts per million.</p> <p>2 Q. Dr. Najafi, for purposes of this</p> <p>3 question, I'm going to ask you to assume that the</p> <p>4 reporting threshold for valsartan API is 0.05</p> <p>5 percent. 240.1 parts per million would be less than</p> <p>6 half of that reporting threshold on a chromatogram.</p> <p>7 Correct?</p> <p>8 MR. NIGH: Form objection.</p> <p>9 A. I take your word for it.</p> <p>10 Q. Dr. Najafi, I'm not asking you to take</p> <p>11 my word for it. I do ask you to assume the reporting</p> <p>12 threshold for purposes of this question. But</p> <p>13 assuming that that is the reporting threshold, at</p> <p>14 0.05 percent, is it accurate that 240.1 parts per</p> <p>15 million of an NDMA impurity in the valsartan API</p> <p>16 would be less than half of that reporting threshold?</p> <p>17 MR. NIGH: Form objection, vague.</p> <p>18 A. Okay.</p> <p>19 (Court Stenographer clarification.)</p> <p>20 MR. HARKINS: Did you hear that? Can</p> <p>21 you just say your answer again, Dr. Najafi, for the</p> <p>22 court reporter.</p> <p>23 A. Yes.</p> <p>24 Q. Dr. Najafi --</p> <p>25 MR. HARKINS: And you can take the</p>
<p style="text-align: right;">Page 319</p> <p>1 milligram pills that you're talking about?</p> <p>2 (Simultaneous speaking.)</p> <p>3 (Court Reporter Clarification.)</p> <p>4 Q. The reference that you wrote about the</p> <p>5 milligrams of pills is on the prior page. But in the</p> <p>6 next page of your report, at the bottom of this</p> <p>7 section, in the paragraph that begins, "ZHP also</p> <p>8 manufactured," there are references to reported</p> <p>9 levels of impurities in parts per million.</p> <p>10 A. Correct.</p> <p>11 Q. And one that is 240.1.</p> <p>12 And my question is: Are you aware of</p> <p>13 any higher level of NDMA or NDEA impurities reported</p> <p>14 in any valsartan API?</p> <p>15 A. 240 -- yeah, 240 -- you know, there</p> <p>16 might be, that's what I was shown, that's what the</p> <p>17 document is pointed -- I pointed to.</p> <p>18 (Cell phone ringing.)</p> <p>19 A. Let me turn off my phone; I'm sorry.</p> <p>20 Q. Just to confirm --</p> <p>21 A. Yeah.</p> <p>22 Q. You are not aware, based on documents</p> <p>23 that you have reviewed, of any higher level reported</p> <p>24 in valsartan API. Correct?</p> <p>25 A. I am not aware, but there may be other,</p>	<p style="text-align: right;">Page 321</p> <p>1 report down for a moment.</p> <p>2 Q. During questioning last week, you</p> <p>3 discussed how Emery Pharma assists manufacturers with</p> <p>4 testing. Do you recall that, generally?</p> <p>5 A. Yes, I do.</p> <p>6 Q. And one of the things that you said,</p> <p>7 when releasing product or assisting with releasing</p> <p>8 product, is that you provide your clients with a</p> <p>9 certificate of analysis. Is that correct?</p> <p>10 A. That's correct.</p> <p>11 Q. The certificate of analysis contains</p> <p>12 information on tests that were performed on either</p> <p>13 that drug substance or a drug product. Right?</p> <p>14 A. That's correct.</p> <p>15 Q. Are those the tests that are required by</p> <p>16 the approved specifications for that drug substance</p> <p>17 or drug product?</p> <p>18 A. What tests are you referring to?</p> <p>19 Q. That's kind of my question. Do you do</p> <p>20 limited testing, as requested by the client? Or do</p> <p>21 you perform complete testing of a drug substance or a</p> <p>22 drug product, such that they could release the</p> <p>23 product without further testing? That's really my</p> <p>24 question.</p> <p>25 MR. NIGH: Form objection.</p>

<p style="text-align: right;">Page 322</p> <p>1 A. It depends on the product. It depends 2 on what the client is asking us to do. In this case, 3 if we were to -- given an API and say, do -- take a 4 look at the -- here is the certificate of analysis 5 from the manufacturer, let's say, ZHP; and typically, 6 it should contain seven solvents, and do residual 7 solvent analysis. 8 And if they do a residual solvent 9 analysis, and if they're supposed to have seven 10 solvents, and we see 20 different peaks, I think we 11 immediately contact the client and say, we're seeing 12 far too many peaks here. 13 Which is really what Novartis saw. And 14 we communicate that to the client and say, "What do 15 you want us to do? You know, we need to investigate 16 these other peaks." 17 In this case, you know, 240 parts per 18 million, this translates into -- one nanogram per 19 milligram translates into one parts per million. 20 Right? One nanogram per milligram; that's one part 21 per million. Now, if you are -- 22 Q. Given that I have very limited time -- I 23 almost never want to interrupt, but this is not 24 remotely responsive. 25 MR. NIGH: Let's go ahead. Let's go</p>	<p style="text-align: right;">Page 324</p> <p>1 We often have some chromatograms associated with 2 them. We provide them with all that documentation, 3 plus a certificate of analysis. 4 Q. Okay. And I understand that you 5 sometimes do that. Do you sometimes also just 6 provide them with a certificate of analysis? 7 A. Almost always not. 8 Q. We discussed, during your testimony last 9 week, the April 2021 483 that Emery Pharma received. 10 Do you recall that? 11 A. Yes, I do. 12 Q. Do you recall that discussion? 13 A. Yes, I do. 14 Q. And I understand from your testimony 15 that, at some point after receiving that, the issues 16 identified in that 483 were addressed by Emery 17 Pharma. Correct? 18 MR. NIGH: Form objection. 19 A. That's correct. 20 Q. Was Emery Pharma continuing to perform 21 testing and assisting with the release of product for 22 its customers in April of 2021? 23 MR. NIGH: Form objection. 24 A. Yes, we continued testing and releasing 25 product, post inspection.</p>
<p style="text-align: right;">Page 323</p> <p>1 ahead. I think it's been answered, too. You can ask 2 the next question. 3 MR. HARKINS: Okay. 4 Q. Dr. Najafi, if my question is confusing 5 or you're unsure what I'm asking, let me know, so I 6 can kind of try and keep us on track. 7 All I'm asking is: Does Emery Pharma 8 sometimes do all of the tests required by a 9 certificate of analysis for release of a finished 10 drug substance -- or for release of a drug substance? 11 MR. NIGH: Form objection. 12 A. We always do what is necessary to 13 release a drug substance. In this case, if we had 14 been tasked for releasing ZHP, we would not have 15 released it. 16 Q. Understood. 17 When you provide your clients with the 18 results of testing, do you provide them with the 19 certificate of analysis, or do you also provide them 20 with all of the raw chromatography and other testing 21 data that supports the results in the certificate? 22 MR. NIGH: Form objection. 23 A. It depends. Often we provide them with 24 a report, a full report with chromatograms; be it, 25 you know, what are some of the prescribed testing.</p>	<p style="text-align: right;">Page 325</p> <p>1 Q. And then you continued to do that, while 2 you were working to correct the issues identified in 3 the 483. Correct? 4 MR. NIGH: Form objection. 5 A. I think I mentioned that in my 6 testimony, that the FDA allowed us to continue our 7 release or testing, because they found no issues with 8 our testing protocols and the chemistry of the work 9 we did. 10 Q. And you did not consider any of the 11 product released by Emery Pharma, during the time 12 that the issues identified in that 483 were present, 13 to be adulterated? 14 MR. NIGH: Form objection. 15 A. That's correct. 16 Q. And you didn't take any steps to remove 17 any of that product released, based on testing 18 performed by Emery Pharma, during that time from the 19 market? 20 MR. NIGH: Form objection. 21 A. That's correct, because the 483 was not 22 related to the actual testing. 23 Q. Understood. And you didn't take any 24 steps to inform patients or physicians about any 25 concerns about product quality, for product that was</p>

<p style="text-align: right;">Page 326</p> <p>1 released during the time that those issues were 2 present and being corrected. Correct? 3 MR. NIGH: Form objection. 4 A. That's correct, because the 483 was not 5 related to testing. However, we did inform the -- 6 many of our clients that we had this 483. 7 Q. And just to confirm: When you're saying 8 "clients," you mean the manufacturers, not patients 9 and physicians and things like that. Right? 10 A. That's correct. 11 Q. But you testified just a little bit ago 12 that you perform required testing on products that 13 you're releasing to the market, which may or may not 14 be all of the tests required in the certificate of 15 analysis. Is that fair? 16 A. Could you repeat your question? 17 Q. Sure. That was a poor question. Let me 18 strike that and just move on. 19 A. I think it was a statement. 20 Q. A lot of times, they sound like that. 21 Dr. Najafi, does Emery Pharma have 22 GC-MS? 23 A. Yes, we do. 24 Q. Do you test all the products released by 25 Emery Pharma using GC-MS?</p>	<p style="text-align: right;">Page 328</p> <p>1 monograph is out the window. 2 Q. Understood. 3 Dr. Najafi, are you familiar with how 4 many USP-approved monographs there are? 5 A. No, I'm not. 6 Q. I'll represent to you, for purposes of 7 this next question, that as stated in the expert 8 report of plaintiffs' retained expert, Dr. Laura 9 Plunkett, there are over 5,000. Okay? And that's 10 just an assumption for the purposes of this next 11 question. All right? 12 Assuming she is correct and there are 13 over 5,000 monographs, are you aware of how many of 14 those require the use of GC-MS testing to perform a 15 specific assay? 16 A. I'm not sure. 17 Q. Coming back to the testing performed at 18 Emery Pharma, when you perform release testing on 19 product -- well, strike that. 20 Let me start with a question before 21 that. 22 Dr. Najafi, what is structural 23 characterization? 24 A. Structural characterization, it refers 25 to what the molecular structure looks like.</p>
<p style="text-align: right;">Page 327</p> <p>1 MR. NIGH: Form objection. 2 A. It depends on the product, and depends 3 on the specifications associated with the product. 4 Q. And when you say "specifications," 5 you're referring to the monograph USP specifications? 6 MR. NIGH: Form objection. 7 A. It might be the monograph from -- 8 monograph from the USP; it might be the client's 9 monograph. It all depends. 10 Q. Are you familiar, generally, with USP 11 monographs and where they can be accessed? 12 A. We are a subscriber to USP, so we have 13 access to it, yes. 14 Q. And as you said, the monographs set out 15 certain testing to be performed on drug substances 16 and drug products. Is that fair? 17 A. That's correct. However -- can I 18 continue? 19 Q. You can continue if you need, yes. 20 A. Yes. However, USP monogram -- monograph 21 sets the minimum standard, and it's often related to 22 the brand, you know, that was -- that had patents on. 23 Once that USP -- once the product is modified, 24 procedures are changed, the manufacturing is changed; 25 pretty much all the impurity related to that</p>	<p style="text-align: right;">Page 329</p> <p>1 Q. In the context of an unidentified 2 impurity that shows up on a chromatogram, what is 3 structural characterization? 4 A. It means identifying what that impurity 5 is. And characterizing it from often multiple 6 different angle: Characterizing it by mass, 7 characterizing it by checking against reference 8 standards, potentially characterizing it by NMR, 9 separating it. So there's a whole list of things 10 that we conduct if we're tasked for characterizing an 11 impurity. 12 Q. And structural characterization of an 13 unidentified impurity would then enable you to 14 determine what specifically that impurity is. Right? 15 A. Exactly. 16 Q. Does Emery Pharma include structural 17 characterization of every impurity -- of every -- 18 strike that. 19 Does Emery Pharma perform structural 20 characterization of every unidentified impurity on 21 chromatograms for products that it releases? 22 MR. NIGH: Form objection. 23 A. We're not a pharmaceutical company, and 24 we're not a manufacturer. We do what the clients ask 25 us to do, and we follow prospectively their</p>

<p style="text-align: right;">Page 330</p> <p>1 prescribed procedure or monograph.</p> <p>2 However, if we see -- you know, we have</p> <p>3 clients that come to us repeatedly with the same</p> <p>4 product that we need to release. We may release it</p> <p>5 once. And then next time we release it, if we see</p> <p>6 the same impurity, same place, same location, our</p> <p>7 internal team often brings that up and say, "This</p> <p>8 impurity is showing up over and over again." And we</p> <p>9 often alert the client that we need to -- we</p> <p>10 should -- we recommend they identify it. And</p> <p>11 identification of impurities, especially in --</p> <p>12 Q. Dr. Najafi, I have very limited time</p> <p>13 with you --</p> <p>14 A. -- is very easy.</p> <p>15 (Court Reporter Clarification.)</p> <p>16 Q. Dr. Najafi -- and I appreciate, and I</p> <p>17 understand your general comments there. My question</p> <p>18 is a little more specific.</p> <p>19 Emery Pharma does not perform structural</p> <p>20 characterization of every unidentified impurity that</p> <p>21 shows up on the chromatogram in release testing that</p> <p>22 it performs for its clients. Correct?</p> <p>23 MR. NIGH: Form objection.</p> <p>24 A. We do what the clients ask us to do.</p> <p>25 You know, if Novartis comes to us and say, "We saw</p>	<p style="text-align: right;">Page 332</p> <p>1 unidentified impurity, you're not discovering a new</p> <p>2 chemical compound, typically. Right?</p> <p>3 MR. NIGH: Form objection.</p> <p>4 A. What do you mean by a "new chemical</p> <p>5 compound"?</p> <p>6 Q. Sure. When you perform structural</p> <p>7 characterization to determine that something is NDMA,</p> <p>8 that is not to say that NDMA was previously unknown</p> <p>9 to science; it's that it was unknown to be -- or</p> <p>10 unidentified as present in this particular substance.</p> <p>11 Is that accurate?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. You know, there are really -- there's no</p> <p>14 new discoveries to be made. However, it could be.</p> <p>15 You know, sometimes the unidentified impurity is</p> <p>16 completely a novel compound, never been reported.</p> <p>17 Sometimes. Most often, what we discover as an</p> <p>18 unknown impurity you could actually, you know, look</p> <p>19 into the literature and see, you know, what -- who</p> <p>20 else has reported this impurity.</p> <p>21 Q. I think I understand your answer.</p> <p>22 You mentioned that ICH Q3A and Q3B</p> <p>23 contain guidance on the identification of</p> <p>24 unidentified impurities in both drug substances and</p> <p>25 drug products. Is that fair?</p>
<p style="text-align: right;">Page 331</p> <p>1 this chromatogram. We're trying to identify what are</p> <p>2 all these impurities," we do it for them. But we</p> <p>3 typically do what the clients want us to do.</p> <p>4 Q. So unless a client asks you to perform</p> <p>5 structural characterization of every unidentified</p> <p>6 impurity for a given product, you would not undertake</p> <p>7 structural characterization of every unidentified</p> <p>8 impurity in products tested and released by Emery</p> <p>9 Pharma. Correct?</p> <p>10 MR. NIGH: Form objection.</p> <p>11 A. Yes, we are not a manufacturer. We're</p> <p>12 not responsible for their product. They are</p> <p>13 responsible for their product.</p> <p>14 Q. Understood.</p> <p>15 Dr. Najafi, are there unidentified</p> <p>16 impurities that you do not perform structural</p> <p>17 characterization on, that are present in product that</p> <p>18 is released, based on testing performed by Emery</p> <p>19 Pharma?</p> <p>20 MR. NIGH: Form objection.</p> <p>21 A. Yes, there are unidentified peaks that</p> <p>22 we often do not identify. However, if the client</p> <p>23 asks us to identify them, we identify them.</p> <p>24 Q. And just to make sure that I'm clear on</p> <p>25 this. When you do structural characterization of an</p>	<p style="text-align: right;">Page 333</p> <p>1 A. I think Q3A points to genotoxins, and --</p> <p>2 you know, identifying them. And, you know, Q3A is</p> <p>3 concerned for genotoxic impurities, as it relates to</p> <p>4 presence of genotoxic impurities in residual solvent</p> <p>5 analysis and so forth.</p> <p>6 Q. And I want to be clear. Is it your</p> <p>7 understanding that ICH Q3A and B make specific</p> <p>8 recommendations for genotoxic substances?</p> <p>9 MR. NIGH: Form objection.</p> <p>10 A. Yes, they do.</p> <p>11 Q. Okay.</p> <p>12 MR. HARKINS: And if I could ask for</p> <p>13 some assistance introducing one of the exhibits that</p> <p>14 I've placed in the private share folder. It's the</p> <p>15 ICH Q3A guidance, which I believe will be marked as</p> <p>16 Exhibit 18.</p> <p>17 (Exhibit Najafi-18, FDA Document</p> <p>18 entitled "Guidance for Industry, Q3A Impurities in</p> <p>19 New Drug Substances," Revision 2 dated June 2008, No</p> <p>20 Bates, 17 Pages, was received and marked for</p> <p>21 identification.)</p> <p>22 Q. Dr. Najafi, now, I'd like you to be able</p> <p>23 to review this. It should be included in the Dropbox</p> <p>24 as well, to the extent you need to.</p> <p>25 Are you familiar with this Q3A,</p>

<p style="text-align: right;">Page 334</p> <p>1 "Guidance For Industry, Impurities in New Drug 2 Substances"? 3 A. Yes, I am. I don't -- I don't have this 4 guidance in the -- in the Drop -- in the -- in the 5 share folder. 6 THE VIDEOGRAPHER: It should be there if 7 you refresh the page. 8 A. Okay, got it. Yes. 9 Q. All right. Dr. Najafi, do you now have 10 access to the document? 11 A. Yes, I do. 12 Q. I'd like you to turn to page 10 of the 13 guidance. 14 A. Okay. 15 THE VIDEOGRAPHER: Is that PDF page 10 16 or document page 10? 17 MR. HARKINS: It will be page 10 of the 18 guidance itself. It's page 13, I believe, of the 19 PDF. 20 Q. All right. Dr. Najafi, you see here how 21 ICH Q3A defines an unidentified impurity? Do you see 22 that definition, the second from the bottom? 23 A. Ten? Okay. 24 Q. Are you there? 25 A. Second from the bottom. "Unidentified</p>	<p style="text-align: right;">Page 336</p> <p>1 undetected. 2 Q. Understood, and I do appreciate that 3 clarification. 4 Dr. Najafi, my question is: Are you 5 aware of any structural characterization of NDMA or 6 NDEA impurities in valsartan API that occurred prior 7 to June 2018? 8 MR. NIGH: Form objection. 9 A. Not in valsartan in particular, but I 10 think there were hints of nitrosation of valsartan by 11 Dr. Lee, in -- prior to June of 2018, and there is 12 plenty of evidence that NDMA is just created from 13 sodium nitrite. 14 Q. And I understand that's your opinion, 15 Doctor, I think it's well-established, and I'm not 16 trying to dispute that. I'm just asking to confirm 17 that hints of nitrosation or those other things 18 you're referring to, those are not structural 19 characterization of the impurity. Correct? 20 MR. NIGH: Form objection. 21 A. I believe it's structural 22 characterization. There were some structural 23 characterization of nitrosated valsartan, or maybe it 24 was losartan, or the other sartans. I'd have to 25 refer back to that testimony.</p>
<p style="text-align: right;">Page 335</p> <p>1 impurity," [inaudible]. Yep. 2 Q. And -- 3 A. I see it. 4 Q. And you see the definition here: "An 5 impurity for which a structural characterization has 6 not been achieved, and that is defined solely by 7 qualitative analytical properties (e.g. 8 chromatographic retention time)." 9 Is that correct? 10 A. That's correct. 11 Q. You are not aware of any structural 12 characterization of NDMA in valsartan drug substance, 13 prior to June of 2018, are you? 14 MR. NIGH: Form objection. 15 A. NDMA has been around since the late 16 '70s, and it is a volatile impurity. 17 Q. Dr. Najafi, my question is about the 18 impurity in API, valsartan API, not any other 19 context; and whether you're aware that it has been 20 structurally characterized in valsartan API? 21 A. I will -- I will attest to you that in 22 chromatograms of the API, NDMA will be invisible. It 23 will be there, but it will be invisible. Because it 24 has no UV activity. Almost all chromatography is 25 done with a UV detector. And NDMA is there, but it's</p>	<p style="text-align: right;">Page 337</p> <p>1 Q. And I'm sorry, so now you're saying you 2 do believe that someone performed a structural 3 characterization of NDMA or NDEA in valsartan, prior 4 to June 2018? 5 A. There were hints of characterized 6 impurities of -- nitrosated impurities of a sartan. 7 And that's -- it was actually from a testimony of 8 Dr. Lee. 9 Q. Dr. Najafi, I want to be real clear. 10 I believe I understand what you just 11 described as the steps that you would take to perform 12 a structural characterization. Are you aware of 13 those steps being taken by anybody with respect to 14 valsartan drug substance, prior to June 2018? 15 MR. NIGH: Object to form; it's been 16 asked and answered. 17 A. As I mentioned to you before, the only 18 thing that I'm aware of is Dr. Lee's testimony, which 19 you can actually bring it up. And there is a 20 reference to ZHP doing some analysis of a -- they 21 were aware that there is a nitrosation happening, 22 because they saw nitrosation of a sartan. It doesn't 23 have to be valsartan; it could be other sartans. 24 Q. Dr. Najafi, are you aware of any 25 information that was known to Teva or the other</p>

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<p>1 finished dose manufacturer, Torrent, on the 2 structural characterization of any nitrosamine 3 impurities in valsartan drug substance prior to 4 June 2018?</p> <p>5 A. They might have been aware, I don't 6 know. I have -- I have not been provided any 7 documents that points to the fact that they were 8 aware.</p> <p>9 Q. Doctor, if you can go ahead and turn to 10 the next page of the Q3A guidance. At the top, it 11 indicates "Attachment 1, Thresholds."</p> <p>12 A. What page are you talking about?</p> <p>13 Q. It's the very next page: Number 11 on 14 the document, number 14 in the PDF.</p> <p>15 A. Okay.</p> <p>16 Q. Let me know when you're there.</p> <p>17 A. Yes, I'm here.</p> <p>18 Q. The first column here indicates "Maximum 19 Daily Dose." You would agree that the 320-milligram 20 valsartan pill would fall under the first row: Less 21 than or equal to two grams per day. Correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And the reporting threshold, which is 24 indicated here, is that 0.05 percent that we 25 previously discussed and, as we previously discussed,</p>	<p>1 Q. And according to the ICHQ3 guidance, if 2 the impurity is greater than the identification 3 threshold, which is 0.01, there are certain actions 4 that are taken, including identifying the structure. 5 Do you see that first step?</p> <p>6 A. Could you repeat your question, please? 7 Sorry about that.</p> <p>8 Q. Sure. The starting point for this 9 decision tree is to determine, "Is the impurity 10 greater than the identification threshold?" 11 You see that. Correct?</p> <p>12 A. Right, exactly.</p> <p>13 Q. And maybe this will short-circuit it. 14 If the impurity is not greater than the 15 identification threshold, the ICH guidance Q3A 16 indicates that no action should be taken. Is that 17 correct?</p> <p>18 A. Correct.</p> <p>19 MR. HARKINS: Let's go ahead and take 20 that down. I'd like to introduce the next exhibit. 21 It's going to be ICH Q3B. 22 (Exhibit Najafi-19, FDA Document 23 entitled "Guidance for Industry, Q3B(R2) Impurities 24 in New Drug Products," Revision 3, August 2006, No 25 Bates, 18 Pages, was received and marked for</p>
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<p>1 that reporting threshold would be more than double 2 the maximum reported amount of nitrosamine in ZHP 3 valsartan API that you are aware of. Correct?</p> <p>4 A. Correct.</p> <p>5 Q. And the Identification Threshold, which 6 is the next column, has a value of 0.10 percent. 7 Correct?</p> <p>8 A. That's correct.</p> <p>9 Q. But that identification threshold would 10 be more than four times higher than the 240.1 parts 11 per million, which is the highest level of reported 12 NDMA in any valsartan API of which you are aware. 13 Correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Dr. Najafi, I'd like to turn to the -- 16 page 13 of the document. And this is page 16 in the 17 PDF. This contains, under Attachment 3, a graph for 18 "Decision Tree For Identification and Qualification." 19 Do you see that?</p> <p>20 A. That's correct.</p> <p>21 Q. Now, this does not provide any 22 instructions as far as the reporting threshold, which 23 was that smaller threshold. Let me know if you 24 disagree; I don't see it on here.</p> <p>25 A. That's correct.</p>	<p>1 identification.) 2 (Court Stenographer clarification.) 3 (A discussion is held off the record.) 4 THE VIDEOGRAPHER: Going off the video 5 record. The time is 10:40 am. 6 (A brief recess takes place.) 7 THE VIDEOGRAPHER: We're back on the 8 video record; the time is 10:50 a.m. 9 MR. HARKINS: Thank you, Dr. Najafi, 10 those are all the questions I have for you. I'm 11 going to turn it over for counsel for Torrent, who 12 may have some additional questions. 13 EXAMINATION BY MS. NAGLE: 14 Q. Hi, Dr. Najafi. How are you? My name 15 is Brittney Nagle, and I -- 16 A. I'm good, thank you. 17 Q. I represent the Torrent defendants. And 18 I have just a handful of quick clarifying questions 19 that relate back to some of your testimony earlier, 20 that you gave when you were being questioned by 21 Mr. Harkins. 22 Dr. Najafi, did you review any Torrent 23 documents to determine what information was available 24 to Torrent from the ZHP DMF? 25 A. I might have reviewed some documents,</p>

<p style="text-align: right;">Page 342</p> <p>1 but are you -- do you have a specific question?</p> <p>2 Q. So my question -- you testified earlier</p> <p>3 that you were not -- you were not aware of what</p> <p>4 documents Teva reviewed, as it related to ZHP's DMF;</p> <p>5 and I want to know if the same is true of Torrent?</p> <p>6 A. I've only reviewed what was provided to</p> <p>7 me through the lawyers, so.</p> <p>8 Q. Okay. Also earlier during your</p> <p>9 testimony, you confirmed for Mr. Harkins that when</p> <p>10 you say the finished dose manufacturers "rushed and</p> <p>11 accepted the risk," that was based on your assumption</p> <p>12 that they must have rushed because they didn't</p> <p>13 identify the impurity, and not based on an</p> <p>14 independent review of documents from Teva.</p> <p>15 Do you remember that?</p> <p>16 MR. NIGH: Form objection.</p> <p>17 A. It is my conclusion that -- based on the</p> <p>18 fact that they allowed the genotoxic impurity to be</p> <p>19 released in the drug product.</p> <p>20 And Novartis just did a temp hold</p> <p>21 GC-FID, GC-F -- GC-FID. And by GC-FID, they were</p> <p>22 able to see a lot of impurities, and they didn't want</p> <p>23 to take that chance. They could have -- they could</p> <p>24 have gone ahead too, but they didn't.</p> <p>25 Q. Okay. So just to be clear, that's</p>	<p style="text-align: right;">Page 344</p> <p>1 question I have for you, Dr. Najafi, thank you.</p> <p>2 MR. NIGH: Okay. Let's go ahead and</p> <p>3 take a break and go into the breakout room.</p> <p>4 THE VIDEOGRAPHER: Going off the video</p> <p>5 record. The time is 10:54 a.m.</p> <p>6 (A brief recess takes place.)</p> <p>7 THE VIDEOGRAPHER: We are back on the</p> <p>8 video record. The time is 11:05 a.m.</p> <p>9 MR. NIGH: Okay. It's my understanding</p> <p>10 that Torrent, Teva and ZHP have finished their</p> <p>11 questioning. There's nobody else on the defense</p> <p>12 side, right?</p> <p>13 MR. HARKINS: Correct.</p> <p>14 MS. ROSE: Yep.</p> <p>15 MR. NIGH: Okay. At this time, we don't</p> <p>16 have any other questions; we're done. Thank you.</p> <p>17 THE VIDEOGRAPHER: Going off the video</p> <p>18 record; the time is 11:05 a.m.</p> <p>19 (The proceedings concluded at 11:05 a.m.</p> <p>20 Pacific Time)</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 343</p> <p>1 not -- that opinion is not based on documents you</p> <p>2 reviewed from Torrent. Correct?</p> <p>3 A. I have reviewed a lot of documents. I</p> <p>4 do not recall specifically, you know, any</p> <p>5 chromatogram. But if you have anything you want to</p> <p>6 share with me, I'll be happy to review, give you my</p> <p>7 opinion.</p> <p>8 Q. Okay. So that leads to my next</p> <p>9 question, which is: Did you review and evaluate any</p> <p>10 of the chromatography testing for API that Torrent</p> <p>11 performed?</p> <p>12 MR. NIGH: Form objection.</p> <p>13 A. I do not recall.</p> <p>14 Q. Okay. And Dr. Najafi, have you seen any</p> <p>15 evidence that Torrent was aware of the potential</p> <p>16 nitrosamine formation in the API or valsartan</p> <p>17 products prior to June 2018?</p> <p>18 A. I cannot know if they were aware. You</p> <p>19 know, I've reviewed a lot of documents, but I am not</p> <p>20 aware of documents specifically pointing to the fact</p> <p>21 that they were aware.</p> <p>22 Q. Okay. That was all --</p> <p>23 A. From the documents that I've reviewed,</p> <p>24 based on the documents that I reviewed.</p> <p>25 MS. NAGLE: Okay. That was the last</p>	<p style="text-align: right;">Page 345</p> <p>1 DANIEL NIGH, ESQ.</p> <p>2 dnigh@levinlaw.com</p> <p>3 January 27, 2023</p> <p>4 RE: In Re: Valsartan, Losartan, Et Al</p> <p>5 1/24/2023, Ramin (Ron) Najafi, PhD (#5677117)</p> <p>6 The above-referenced transcript is available for</p> <p>7 review.</p> <p>8 Within the applicable timeframe, the witness should</p> <p>9 read the testimony to verify its accuracy. If there are</p> <p>10 any changes, the witness should note those with the</p> <p>11 reason, on the attached Errata Sheet.</p> <p>12 The witness should sign the Acknowledgment of</p> <p>13 Deponent and Errata and return to the deposing attorney.</p> <p>14 Copies should be sent to all counsel, and to Veritext at</p> <p>15 cs-nj@veritext.com.</p> <p>16</p> <p>17 Return completed errata within 30 days from</p> <p>18 receipt of testimony.</p> <p>19 If the witness fails to do so within the time</p> <p>20 allotted, the transcript may be used as if signed.</p> <p>21</p> <p>22 Yours,</p> <p>23 Veritext Legal Solutions</p> <p>24</p> <p>25</p>

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JURAT.

I DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony and I certify that is it true and correct to the best of my knowledge.

SWORN AND SUBSCRIBED
BEFORE ME ON THIS
DAY OF 2023

Notary Public of the State of

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ATTACH TO DEPOSITION OF RAMIN (RON) NAJAFI, Ph.D.:
IN THE MATTER OF: VALSARTAN

DATE TAKEN: January 24, 2023

ERRATA SHEET

INSTRUCTIONS: After reading the transcript of testimony, please note any change, addition or deletion on this sheet. DO NOT make any marks or notations on the transcript itself.

Please sign and date this errata sheet
and return it to the court reporter whose name is
shown below.

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DATE and SIGNATURE:

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CERTIFICATE

I, ELLEN J. GODINO, CCR, CRCR, RPR, do hereby
certify that prior to the commencement of the
examination, DR. RAMIN (RON) NAJAFI was duly sworn by
me to testify the truth, the whole truth and nothing
but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Ernest J. Grover

ELLEN J. GODINO

CERTIFIED COURT REPORTER

REGISTERED PROFESSIONAL REPORTER

CERTIFIED REALTIME COURT REPORTER

DATED: January 27, 2023

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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